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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,117	02/22/2006	Richard L. Miller	58751US010	2906

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EXAMINER	
BAEK, BONG-SOOK	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
03/17/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

LegalUSDocketing@mmm.com
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Office Action Summary	Application No.	Applicant(s)	
	10/595,117	MILLER ET AL.	
	Examiner	Art Unit	
	BONG-SOOK BAEK	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11,14,17,20-22,27,34 and 36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8, 11, 14, 17, 20-22, 27, 34, and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In view of the Appeal brief filed on 12/23/2010, PROSECUTION IS HEREBY REOPENED. A new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Ardin Marschel/

Supervisory Patent Examiner, Art Unit 1614

Status of claims

Claims 1-8, 11, 14, 17, 20-22, 27, 34, and 36 are pending. Upon reconsideration, the requirement to elect a species of medical conditions set forth in the office action mailed on 6/9/2008 is hereby withdrawn. Accordingly, withdrawn claim 6 is rejoined. Claims 1-8, 11, 14, 17, 20-22, 27, 34, and 36 are currently under examination.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8, 11, 14, 17, 20-22, 27, 34, and 36 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not reasonably provide enablement for delivering every and each immune response modifier (IRM) compound to various mucosal surfaces so as to achieve immunomodulation with reduced irritation of the mucosal surface from IRM compound by applying the IRM compound in repeated application to the mucosal surface and removing at least 50% of the IRM compound from the mucosal surfaces after each application. In addition, claims 27, 34, and 36 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating a specific condition associated with a mucosal surface such as cervical dysplasia with a IRM compound, does not reasonably provide enablement for the general treatment of conditions associated with any mucosal surface with a IRM compound. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. Attention is directed to In re Wands, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors: (1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill

of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. All factors have been considered together and specifically relevant factors are addressed below:

The instant claims are drawn to a method of delivering an immune response modifier (IRM) compound to a mucosal surface so as to achieve immunomodulation with reduced irritation of the mucosal surface from the IRM compound, comprising interrupted delivery of an IRM compound other than imiquimod by intermittently applying in repeated applications the IRM to the mucosal surface and, after each application, removing from the mucosal surface at least 50% by weight of the IRM that was originally applied in each application at a time before it would otherwise be naturally absorbed or eliminated. The claims are very broad since the claims encompass delivering any IRM compounds, which have diverse chemical structures, and to any mucosal surfaces, which include any body surface with mucous membranes (mucosae) such as gastric mucosa, intestinal mucosa, bronchial mucosae, uterine mucosa, dendometrium, etc.

US 2002/0058674 (already made of record) teaches that some of the beneficial effects of IRMs are known, but the ability to provide therapeutic benefit via topical application of an IRM for treatment of a particular condition at a particular location may be hindered due to tissue irritation, formulation wash away, poor permeation or undesired systemic delivery of the topically applied compound ([0007]). US 2002/0058674 also teaches that topical application is often difficult or impossible due to the anatomical location of the tissue. In some cases, application of the agent to a general anatomical region that includes or surrounds the target tissue may be an alternative to direct topical application. But, if the agent has irritating properties, this alternative disadvantageously carries with it the possibility of irritating tissues surrounding the

target tissue. In addition, even if the agent is non-irritating, regional application typically requires use of a greater volume or concentration of the agent to achieve a therapeutic result equivalent to that achieved by direct application to the target tissue ([0008]). In particular, the uterine cervix is one example of a target tissue to which it is difficult to apply a topical agent. Relative to a standing position, the cervix is typically located at the uppermost portion of the vaginal cavity. However, while the cervix is located at the uppermost portion of the vaginal cavity, age, the stage of the estrous cycle, pregnancy, and other factors cause variability of the location of the cervix between different women and in the same woman at different stages of life ([0009]). In addition, with the exception of certain body orientations, gravity tends to drain agents away from the cervix. Normal discharge and flow of fluids, both menstrual and non-menstrual, also drain away from the cervix ([0011]). Theses teachings demonstrate the difficulty of delivering an appropriate amount of IRM compounds to various mucosal surfaces for optimal treatment with reduced irritation and predicting how much amount of a given IRM compound is naturally absorbed or eliminated from a target mucosal surface after each application.

The absorption or elimination of a given IRM compound applied to mucosal surface can vary depending on various factors: types of IRM compounds, formulation types, types of mucosal surfaces, the size or location of application area, individual patient's condition or body metabolism rate (e.g. some people have faster elimination capacity of drugs), even whether the patient is upright or not as stated above. Thus, such variety of factors would reasonably affect the amount of IRM compounds that would be either absorbed or eliminated naturally at each delivery episode. This multitude of factors indicate that prediction of timing of removing the IRM as claimed would be so complex as to support undue experimentation for practicing the

instant invention in order to satisfy the percentage removal limitation in the claims as well as what time would be predictable. In addition, none of the examples in the specification as filed support a practice that meets the instant claim limitation. The specification only discloses removing the IRM compounds 2, 4, and 6 hours after application (p20-29), however there is no information or measurement as to how much amount of the IRM compound is removed at those times. For purposes of enablement, the specification must provide reasonable detail in order for those skilled in the art to carry out the invention. In this case, the specification must disclose specific details as to how to perform the claimed removing step and the timing of removing a given IRM compound to satisfy the percentage removal limitation in the claims for various IRM compounds with diverse chemical structures and different mucosal surfaces which would affect the amount of IRM compounds either absorbed or eliminated at each delivery episode while achieving the desired therapeutic effects as claimed. Neither the teachings in the art nor the specification provide any direction or guidance so that a person of ordinary skill in the art would be able to practice the claimed complex delivery method without undue experimentation.

In addition, the instant claims 27, 34, and 36 are drawn to the treatment of any conditions associated with any mucosal surfaces, i.e. any types of conditions or disorders occurring in mucosal surface, which may have different etiologies and pathophysiologies including those not associated with immune response such as genetic mucosal disorders (e.g. multiple cutaneous and mucosal venous malformations). IRM compounds act through basic immune system mechanisms known as toll-like receptors to induce selected cytokine biosynthesis. For example, imiquimod, which is a well-known IRM compound, is being used for treating actinic keratoses, superficial basal cell carcinoma, and external genital warts. However, there is no prior art

teaching that IRM compounds are generally useful for any mucosal conditions including such genetic mucosal disorders. Although the specification discloses the effect of IRM compounds on the production of certain cytokines such as TNF and MCP-1, it does not provide any working examples for the treatment of any mucosal conditions. There is no demonstrated correlation that the tests and results disclosed in the specification apply to all types of mucosal conditions or disorders embraced by the instant claims. Furthermore, it is not reasonable to any agent to be able to treat any mucosal conditions or disorders generally regardless of etiologies.

Generally, the relative skill of those in the art of pharmaceuticals and pharmacology is high. However, Applicant has not provided any competent evidence or disclosed tests that are highly predictive for practicing the claimed method for accomplishing the desired result of the claimed invention without undue experimentation. Pharmacological activity in general is a very unpredictable area. Note that in cases involving physiological activity such as the instant case, "the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved". See In re Fischer, 427 F.2d 833, 839, 166 USPQ 10, 24(CCPA 1970).

Due to the large quantity of experimentation necessary to determine how to practice the claimed method, the lack of direction/guidance presented in the specification regarding same, the absence of sufficient working examples directed to same, the complex nature of the invention, and the breadth of the claims, undue experimentation would be required of the skilled artisan to practice the claimed invention in its full scope, with no assurance of success..

Genentech Inc. vs. Nova Nordisk states, "[A] patent is not a hunting license. It is not a reward for a search but a compensation for its successful conclusion and 'patent protection' is

granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" (42 USPQ 2d 1001, Fed. Circuit 1997).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BONG-SOOK BAEK whose telephone number is (571)270-5863. The examiner can normally be reached 9:00 AM-6:00 PM Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-071818. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BONG-SOOK BAEK
Examiner, Art Unit 1614

Bbs

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614